

Application Serial No.: 10/511,577
Int'l Appl. No.: PCT/FR03/01407
Preliminary Amendment Dated May 2, 2005

LISTING OF CLAIMS:

The following listing of claims will replace all prior versions and listing of claims in the present application:

1. (Previously Presented) A packaging (1) intended to be used for transporting sterile objects or objects that are to be sterilized, comprising a box (3) intended to house the sterile objects or objects that are to be sterilized, and a cover sheet (4) fixed to the box in such a way as to seal the latter imperviously;

which packaging is characterized in that said cover sheet is made of a material that is not permeable to a decontamination gas, for example to hydrogen peroxide vapors, and comprises at least one window (6) closed by a piece (7) of selectively impervious material, and in that it further comprises at least one flexible piece (8) of a material that is not permeable to a decontamination gas, for example to hydrogen peroxide vapors, the said flexible piece (8) being fixed to the cover sheet (4) by at least one of its edges (15) and comprising a free part (16), the free part (16) of said piece being able to move between a diffusion position, allowing unrestricted diffusion of sterilization gas into the box (3) through the window (6) and a non-diffusion position minimizing or even preventing the diffusion of decontamination gas, for example of hydrogen peroxide vapors, into the box (3) through the window (6).

2. (Previously Presented) The packaging as claimed in claim 1, characterized in that the selectively impervious material is chosen from paper, materials based on natural or synthetic fibers, materials based on filaments of high density polyethylene, or some other polymer, these being bound in particular by heat and pressure, and combinations thereof.

3. (Previously Presented) The packaging as claimed in claim 2, characterized in that the selectively impervious material is a material based on filaments of high density polyethylene bound by heat and pressure.

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4. (Currently Amended) The packaging as claimed in claim 1 ~~any one of the preceding claims~~, characterized in that the box (3) has a rim (12) extending beyond the cover sheet (4) and the flexible piece (8) is fixed to the exterior face (14) of the cover sheet.

5. (Currently Amended) The packaging as claimed in claim 1 ~~one of claims 1 to 3~~, characterized in that the flexible piece (8) is fixed to the interior face (9) of the cover sheet.

6. (Currently Amended) The packaging as claimed in claim 1 ~~any one of the preceding claims~~, characterized in that the flexible piece (8) is fixed to the cover sheet (4) facing the window (6).

7. (Currently Amended) The packaging as claimed in claim 1 ~~any one of the preceding claims~~, characterized in that the flexible piece (8) has a shape similar to that of the window (6), the area of the flexible piece (8) being greater than that of the window (6) so that in the non-diffusion position, the flexible piece (8) covers this window (6) with overlap around its entire periphery.

8. (Currently Amended) The packaging as claimed in claim 1 ~~any one of the preceding claims~~, characterized in that the cover sheet (4) has several windows (6) each closed by a piece (7) of selectively impervious material.

9. (Previously Presented) The packaging as claimed in claim 8, characterized in that the flexible piece (8) is fixed to the cover sheet (4) facing several windows (6) so that in the non-diffusion position, the flexible piece (8) covers all the windows (6) with overlap.

10. (Previously Presented) The packaging as claimed in claim 8, characterized in that several flexible pieces (8) are fixed to the cover sheet (4), one facing each window (6) so that in the non-diffusion position, each flexible piece (8) covers, with an overlap, the window (6) facing which it is fixed.

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11. (Currently Amended) The packaging as claimed in claim 1 ~~any one of the preceding claims~~, characterized in that it comprises, inside the box, at least one layer (17) limiting the passage of a decontamination gas, for example of hydrogen peroxide vapors, or able to absorb a decontamination gas, for example hydrogen peroxide vapors.

12. (Previously Presented) The packaging as claimed in claim 11, characterized in that the said layer has shape and size such that it can be placed along the cover sheet and that, in this position, it extends between the cover sheet (4) and the objects (2) contained in the packaging.

13. (Currently Amended) The packaging as claimed in claim 11 ~~one of claims 11 to 12~~, characterized in that said layer or at least one of said layers are arranged over the objects placed inside the box prior to the cover sheet being sealed, or on supports provided for that purpose, or on an objects-positioning piece placed in this box.

14. (Currently Amended) A method of manufacturing the packaging (1) as claimed in claim 1 ~~one of claims 1 to 13~~, characterized in that it comprises the steps consisting in:

- forming a cover sheet (4) made of a material that is not permeable to a decontamination gas, for example to hydrogen peroxide vapors, while forming at least one window (6) in this cover sheet;
- placing a piece (7) of a selectively impervious material in said window in such a way as to close this window using this material,
- fixing a flexible piece (8) of a material that is not permeable to a decontamination gas, for example to hydrogen peroxide vapors, over the cover sheet, said flexible piece (8) being fixed to the cover sheet (4) by at least one of its edges (15) and comprising a free part (16), said free part (16) being positioned facing the window (6),
- placing the objects (2) that are to be packaged in a box (3), and
- fixing said cover sheet (4) over the box (3) in such a way as to seal this box imperviously.

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15. (Previously Presented) The method as claimed in claim 14, characterized in that the flexible piece (8) is fixed to the exterior face of the cover sheet (4).

16. (Previously Presented) The method as claimed in claim 14, characterized in that the flexible piece (8) is fixed to the interior face of the cover sheet (4).

17. (Currently Amended) The use of the packaging (1) as claimed in claim 1 ~~one of claims 1 to 13~~ in a method for decontaminating this packaging using a decontamination gas, for example using hydrogen peroxide vapors.

18. (Currently Amended) The use of the packaging (1) as claimed in claim 1 ~~one of claims 1 to 13~~ for transporting syringe components, particularly syringe bodies (2) which are intended to be filled later with an active product or a medicinal product.

19. (Currently Amended) A sterilization and decontamination method using a packaging (1) as claimed in claim 1 ~~any one of claims 1 to 13~~, characterized in that it comprises the steps consisting in:

- placing the packaging (1) in a diffusion position during the sterilization process; and
- placing the packaging (1) in a non-diffusion position during the decontamination process.